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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/661,406

09/12/2003

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ENDOS 64190

6647

24201 7590 07/09/2009
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EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

07/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/661,406	Applicant(s) WU ET AL.	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4,6-9,13 and 15-19 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4,6-9,13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>102108</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Prosecution on the merits of this application is reopened. Applicant is advised that the Notice of Allowance mailed 09/12/08 is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.
2. The indicated allowability of claims 2, 4, 6-9, 13, 15-19 is withdrawn in view of the newly discovered reference(s) to Randall (US 6,514,261). Rejections based on the newly cited reference(s) follow.

35 USC § 112 Sixth Paragraph

3. It is presumed that applicant has intended to invoke 112 sixth paragraph as per the means for language set forth in the claims.
 - a. In Claim 4, “means for evacuating air” is interpreted by the specification to be openings in the inner catheter or equivalents thereof.
 - b. In Claim 11, “means for preventing unintentional movement of the gear rack” is interpreted by the specification to be a locking arm or equivalents thereof
 - c. In claim 12 and 14, “means for allowing motion of the gear rack in only one direction” is interpreted by the specification to be a spring or equivalents thereof.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2, 13, 15, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Randall et al. (US 6,514,261) in view of Kavteladze (US 5,707,376) further in view of Sullivan III (US 5,968,052).

7. Randall discloses a system for delivering a medical device within a patient (Fig. 13 and 14), comprising: a delivery catheter including an inner catheter (14) having a region for mounting the medical device (stent) (16); an outer restraining member (10) co-axially over the inner catheter member (14) and the medical device (16); the outer restraining member being adapted for axial movement with respect to said inner catheter member (C7:L4-16); a control handle (82) having a rotatable thumbwheel (90)

connected to a retraction mechanism, the inner catheter member having a proximal end attached to the control handle and the outer restraining member having a proximal end attached to the retraction mechanism, wherein rotation of the thumbwheel causes linear movement of the retraction mechanism to proximally retract the outer restraining member to uncover the medical device while the inner catheter remains stationary (C7:L4-16), wherein the retraction mechanism includes a gear rack (84) slidable within a channel and a spur gear (88) which engages gears of the gear rack, the thumbwheel having an actuating gear (92) which engages with the spur gear to move the gear rack linearly when the thumbwheel is rotated. The inner catheter includes a guide wire lumen extending from the proximal end to the distal end of the inner catheter (38)

8. Randall does not disclose a stop means for preventing unintentional movement of the gear rack. However Kavteladze discloses a stent delivery device (Fig. 2) with a handle (10) that incorporates the use of a rotating actuator (21) similar to Randall for retracting the restraining member (45). Kavteladze incorporates a stop means or lock (28) for preventing unintentional movement of the gear rack (C7:L31-38). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the lock mechanism into the device of Randall in order to prevent unwanted movement of the restraining member while the stent is being properly positioned as taught by Kavteladze.

9. Randall modified by Kavteladze does not disclose a means for allowing motion of the gear rack in only one direction. However Sullivan discloses the use of a spring (92) having an edge that engages the surface of the gear rack to allow motion of the gear

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rack in only one direction and prevent distal movement of the gear rack (C5:L5-10). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a spring for preventing proximal movement of the gear rack as taught by Sullivan. The use of a thumbwheel does not allow for one single continuous motion for retracting the restraining member. Rather it requires several rotations where the user would need to lift the thumb in between. During the brief period of lifting the thumb to engage in another rotation of the actuator, any movement of the handle could result in movement of the restraining member. One of ordinary skill would only need common sense to determine that it would be an advantage to prevent the sheath from moving distally during this time. Sullivan provides the teaching of using a spring to achieve this goal. A person of ordinary skill has good reason to pursue the known options within his or her technical grasp, such as the use of a spring, if it yields the predictable results of preventing distal movement of the gear rack and thus the restraining member.

10. Regarding claim 15, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate an anti-clotting agent into a stent delivery device since it is well known in the art to deliver drugs at the time of stent delivery to prevent further trauma to the tissue that is being treated. Since applicant failed to traverse examiner's assertion, the common knowledge or well-known in the art statement is taken to be admitted prior art (MPEP 2144.03 C).

11. Claims 6, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Randall in view of Kavteladze and Sullivan as applied to claim 13 above and further in view of Fitz (USPN 6,146,415).

12. Randall modified by Kavteladze and Sullivan discloses the invention substantially as claimed as stated above except for an outer sheath. However, Fitz discloses a stent delivery system that comprises an inner catheter (10), a restraining sheath (16) as well as a guide catheter with a coupling member (40) wherein the position of the catheter handle can be fixed with respect to the guide catheter to prevent unwanted movement of the device during delivery thereby providing greater accuracy of stent placement (C6:L56-62). The guide catheter facilitates advancement of the of the stent delivery system through the vasculature (C6:L40-46). The guide catheter is removably attached (50) to the control handle (24) thereby allowing it to be delivered separately as well as allowing the position of the outer sheath to be adjusted (C7:L49-67). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a removable sheath in order to provide the enhancements taught by Fitz.

13. Regarding claim 16, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate an anti-clotting agent into a stent delivery device since it is well known in the art to deliver drugs at the time of stent delivery to prevent further trauma to the tissue that is being treated. Since applicant failed to traverse examiner's assertion, the common knowledge or well-known in the art statement is taken to be admitted prior art (MPEP 2144.03 C).

14. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Randall in view of Kavteladze and Sullivan as applied to claim 13 above and further in view of Stack et al (6,860,898).

15. Randall modified by Kavteladze and Sullivan discloses the invention substantially as claimed as stated above except for the means for evacuating air. Stack discloses a stent delivery device with openings (49) in the catheter for allowing the evacuation of air. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate flushing system including holes for evacuating air since it is well known in the art as evidenced by Stack.

16. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Randall in view of Kavteladze, Sullivan and Fitz as applied to claim 19 above and further in view of Wang (US 7,128,965).

17. Randall modified by Kavteladze, Sullivan and Fitz does not disclose that the outer sheath has a distal end which has a smaller inner diameter than the proximal portion of the sheath. However, Wang discloses a guide catheter that is tapered at the distal end to allow the outer sheath to more readily follow passages that are curved or branched (C5:L23-25). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a tapered distal end on the outer sheath to achieve the same advantage as taught by Wang.

18. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Randall in view of Kavteladze, Sullivan and Fitz as applied to claim 19 above, and further in view of McGlinch (US 2003/0060803).

19. Randall modified by Kavteladze, Sullivan and Fitz does not disclose a removable strain relief. However McGlinch teaches a proximal end of an outer sheath (10) is attached to a strain relief member (34) which is removably attached to the control handle for the purpose of providing a gradual transition between the flexible tubing and the rigid hub thereby preventing kinking (Para [0020]-[0023]).

20. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Randall in view of Kavteladze, Sullivan, Fitz and McGlinch as applied to claim 7 above and further in view of Smutney (US 6,733,465).

Randall modified by Kavteladze, Sullivan, Fitz and McGlinch discloses the claimed apparatus as stated above but does not disclose the claimed mechanism for attaching the strain relief to the handle. However Smutney discloses a coupling mechanism for coupling two hubs of a medical device (Fig. 1a, 1b) including a hub (10) which includes a channel (16a, 16b and 16c) and hub (24) defines a tab like projection (28) for being received within the channel. It would have been obvious to one having ordinary skill in the art at the time of the invention to substitute the coupling mechanism of McGlinch for the coupling mechanism taught by Smutney since the substitution of one known element for another would have yielded predictable results namely a coupling

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mechanism that lockably secures one portion of a device to another thereby preventing separation of the portions during use.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
7/1/09